

**REMARKS**

Claims 1-7 are pending in the current application. Claims 1, 6 and 7 are in independent form. In view of the above amendments and the following remarks, favorable reconsideration and allowance of the present application is respectfully requested.

Initially, Applicant appreciates the Examiner's indication that the references submitted in the Information Disclosure Statements filed on April 20, 2010 and June 11, 2010 have been considered.

I. **SPECIFICATION AMENDMENTS**

By the present Amendment, the Specification is amended. In the present application, Applicant's priority claim to International Patent Application No. PCT/SE03/01892, U.S. Provisional Application No. 60/430,364 and Sweden Application No. 0203569-9 was included in the Declaration filed on December 19, 2006, which was filed within the time period set forth in 37 C.F.R. § 1.78(a). Further, the information concerning the priority claim was recognized by the USPTO as shown by its inclusion in the Official Filing Receipt mailed March 8, 2007 (copy enclosed). Applicant now submits the present Amendment to amend the specification to include specific reference to these priority claims.

MPEP § 201.11.III.D states (emphasis added):

If an applicant includes a benefit claim in the application but not in the manner specified by 37 C.F.R. § 1.78(a) (e.g., if the claim is included in an oath or declaration or the application transmittal letter) within the time period set forth in 37 C.F.R. § 1.78(a), the Office will not require a petition under 37 C.F.R. § 1.78(a) and the surcharge under 37 C.F.R. § 1.17(t) to correct the claim if the information concerning the claim was recognized by the Office as shown by its inclusion on the filing receipt.

Therefore, according to MPEP § 201.11.III.D (recited above), a petition under 37 C.F.R. § 1.78(a) and surcharge under 37 C.F.R. § 1.17(t) are not required.

Applicant requests entry of this amendment to the specification and request proper recognition of this priority claim to International Patent Application No. PCT/SE03/01892, U.S. Provisional Application No. 60/430,364 and Sweden Application No. 0203569-9.

II. CITED ART REJECTIONS

(A) *Claims 1-5 and 7 stand rejected under 35 U.S.C. §102(e) as being anticipated by Anderson et al. (hereinafter “Anderson”), U.S. Publication No. 2002/0168618. Applicant respectfully traverses this rejection.*

i. INDEPENDENT CLAIM 1

Independent claim 1 is directed to an interventional procedure simulation system wherein (*inter alia*) “the control unit is configured to simulate said instrument with respect to a set value representing a stiffness of said vessel, a rest diameter of said self expanding tool, an initial inner diameter of said vessel and a spring constant for said tool.” Applicant submits that Anderson fails to explicitly teach, or otherwise suggest, the above features recited in independent claim 1.

The rejection states that Anderson discloses a control unit “...configured to simulate said instrument with respect to a set value (paragraphs 0023 & 0037: physiological parameters and alter parameters) representing a stiffness of said vessel, a rest diameter of said self expanding tool, an initial inner diameter of said vessel and spring constant for said tool.” Action, p. 2.

However, the set value representing the claimed combination of “a stiffness of said vessel, a rest diameter of said self expanding tool, an initial inner diameter of

said vessel and a spring constant for said tool" is not taught or suggested by Anderson.

In particular, paragraph [0023] of Anderson (as relied upon by the Examiner) states that,

The system can be adapted for use by multiple users, for example, as part of a training environment. In one aspect, the system comprises a monitoring station comprising a second user device connectable to the network and comprising a second display interface for enabling a second user to monitor the movement of the medical device within the simulated body cavity or lumen. Preferably, the second display interface displays selectable options (e.g., a drop down menu, action buttons, check buttons, radio buttons, dialog boxes, command lines and the like), enabling the second user to select or change one or more anatomical and/or physiological parameters of the simulated body cavity or lumen. Selection of a selectable option causes the three-dimensional image of the simulated body cavity or lumen displayed to the first user to change to reflect the changed anatomical and/or physiological parameters selected by the second user.

Emphasis added.

Thus, paragraph [0023] states the system includes a second display interface that allows a second user to (i) monitor the movement of the medical device within the simulated body cavity or lumen, and (ii) to select or change one or more anatomical and/or physiological parameters of the simulated body cavity or lumen wherein such selections or changes cause the 3D image of the lumen display to the first user to change.

Paragraph [0023] of Anderson does not teach, or suggest, that the system is configured to simulate the medical device with respect to a set value representing parameters of the lumen and the tool. Thus, paragraph [0023] of Anderson does not teach, or suggest, that the system is "configured to simulate said instrument with

respect to a set value representing a stiffness of said vessel, a rest diameter of said self expanding tool, an initial inner diameter of said vessel and a spring constant for said tool" as recited in independent claim 1.

Paragraph [0037] of Anderson states that,

A second user also can interact with the first user by using the monitoring station described above. For example, the second user can display a particular image selected by the second user from the database on the first user's display interface. The second user can alter parameters of the simulation displayed to the first user, for example, as part of a training exercise, to document the progress of one or more first users, and/or to introduce procedural variables that can be used to test or evaluate the response and decision-making abilities of one or more first users.

Paragraph [0037] of Anderson does not teach, or suggest, that the system is configured to simulate the medical device with respect to a set value representing "a stiffness of said vessel, a rest diameter of said self expanding tool, an initial inner diameter of said vessel and a spring constant for said tool" as recited in independent claim 1.

Applicant notes that the Examiner states "Anderson et al. does not disclose simulating said at least one instrument with respect to a set value representing a rest diameter of said self expanding tool and a spring constant of said self expanding tool." Action, p. 4.

Absent Applicant's own disclosure, there is no suggestion that the system processor of Anderson is configured to simulate an instrument with respect to a set value representing "a stiffness of said vessel, a rest diameter of said self expanding tool, an initial inner diameter of said vessel and a spring constant for said tool" as recited in independent claim 1.

For at least these reasons, Anderson fails to explicitly teach, or otherwise suggest, an interventional procedure simulation system wherein "the control unit is configured to simulate said instrument with respect to a set value representing a stiffness of said vessel, a rest diameter of said self expanding tool, an initial inner diameter of said vessel and a spring constant for said tool" as recited in independent claim 1.

Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection to independent claim 1, and claims 2-5 at least by virtue of their dependency on independent claim 1.

ii. INDEPENDENT CLAIM 7

Independent claim 7 is directed to an interventional procedure simulation system wherein (*inter alia*) "the control unit is configured to simulate said instrument with respect to a set value representing an stiffness of said simulated vessel, a rest diameter of said self-expanding tool, an initial inner diameter of said simulated vessel, and a spring constant for said self-expanding tool." Thus, independent claim 7 is patentable over Andersen for similar reasons as given above with respect to independent claim 1.

As such, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection to independent claim 7.

(B) *Claim 6 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Anderson in view of Merrill, U.S. Patent No. 6,106,301 and Tarr, U.S. Patent No. 6,191,796 B1. Applicant respectfully traverses the rejection.*

Independent claim 6 is directed to a method of simulating an interventional procedure simulation system including (*inter alia*) "simulating said at least one instrument with respect to a set value representing a stiffness of said simulated vessel, a rest diameter of said self expanding tool, an initial inner diameter of said simulated vessel and a spring constant for said self expanding tool." Applicant submits that the combination of Anderson, Merril and Tarr fail to explicitly teach, or otherwise suggest, the above features of independent claim 6.

Firstly, the rejection states that Anderson discloses a method including "...simulating said at least one instrument with respect to a set value (paragraphs 0023 & 0037: physiological parameters and alter parameters) representing a stiffness of said vessel (paragraph 0068), a rest diameter of said self expanding tool, an initial inner diameter of said vessel (paragraphs 0151 & 0193) and spring constant for said tool." Action, p. 4.

However, the set value representing the claimed combination of "a stiffness of said vessel, a rest diameter of said self expanding tool, an initial inner diameter of said vessel and a spring constant for said tool" is not taught or suggested by Anderson.

In particular, as noted above, paragraph [0023] of Anderson (as relied upon by the Examiner) does not teach, or suggest, that the system is configured to simulate the medical device with respect to a set value representing parameters of the lumen and the tool. Thus, paragraph [0023] of Anderson does not teach, or suggest, that the system is "configured to simulate said instrument with respect to a set value representing a stiffness of said vessel, a rest diameter of said self expanding tool, an initial inner diameter of said vessel and a spring constant for said tool" as recited in independent claim 1. And, paragraph [0037] of Anderson does not teach, or suggest, that the system is configured to simulate the medical device with respect to a set

value representing “a stiffness of said vessel, a rest diameter of said self expanding tool, an initial inner diameter of said vessel and a spring constant for said tool” as recited in independent claim 1.

Paragraph [0093] states that,

The manikin interface can be encased in a housing comprising one or more openings for receiving medical devices, and means for interfacing with tracking unit(s), feedback mechanism(s) and a system processor (described further below). Additional devices such as syringes and balloon inflating devices can be provided as part of the interface, e.g., simulating balloon angioplasty proceedings).

Paragraph [0093] states that device such as syringes and balloon inflating devices can be simulated. Paragraph [0093] does not state that the spring constant of the devices is considered. (Note: The rejection states that “Anderson et al./Merril does not disclose simulating said at least one instrument with respect to a set value representing a spring constant of said self expanding tool.” Action, p. 5.) Thus, paragraph [0093] of Anderson does not teach, or suggest, that the system is configured to simulate the medical device with respect to a set value representing “a stiffness of said vessel, a rest diameter of said self expanding tool, an initial inner diameter of said vessel and a spring constant for said tool” as recited in independent claim 1.

Paragraph [0153] states that, “[q]uantitative measures of a pathology can be obtained. For example, a quantity module which is part of the system can be used to measure the size of a blockage (e.g., a plaque).” Thus, paragraph [0153] implies that a lumen having plaque, for example, has a different size.

Paragraph [0153] does not teach that the system is configured to simulate the medical device with respect to a set value representing parameters of the lumen and the tool. Thus, paragraph [0153] of Anderson does not teach, or suggest, that the

system is configured to simulate the medical device with respect to a set value representing "a stiffness of said vessel, a rest diameter of said self expanding tool, an initial inner diameter of said vessel and a spring constant for said tool" as recited in independent claim 1.

Furthermore, Applicant notes that the Examiner states "Anderson et al. does not disclose simulating said at least one instrument with respect to a set value representing a rest diameter of said self expanding tool and a spring constant of said self expanding tool." Action, p. 4.

Secondly, acknowledging the deficiencies of Anderson, the rejection states that "...Merril teaches simulating said at least one instrument with respect to a set value representing a rest diameter of said self expanding tool (column 9 lines 51-54 & lines 62-66, column 11 lines 29-32, column 12 lines 26-30, column 14 lines 43-46 & lines 52-55)." Action, pp. 4-5.

However, Merril merely teaches that instruments have a diameter. Merril does not teach, or suggest, that the simulation system is configured to simulate the medical device with respect to a set value representing "a stiffness of said vessel, a rest diameter of said self expanding tool, an initial inner diameter of said vessel and a spring constant for said tool" as recited in independent claim 1.

Thirdly, acknowledging the deficiencies of Anderson and Merril, the rejection states that "...Tarr teaches simulating said at least one instrument with respect to a set value representing a spring constant of said self expanding tool (spring constant)." Action, p. 5.

However, Tarr does not teach, or suggest, that the system is configured to simulate the medical device with respect to a set value representing "a stiffness of said vessel, a rest diameter of said self expanding tool, an initial inner diameter of said vessel and a spring constant for said tool" as recited in independent claim 1.

Thus, absent Applicant's own disclosure, there is no suggestion that the system processor of Anderson in combination with Merril and Tarr is configured to simulate an instrument with respect to a set value representing "a stiffness of said vessel, a rest diameter of said self expanding tool, an initial inner diameter of said vessel and a spring constant for said tool" as recited in independent claim 1.

For these reasons, Applicant submits that Anderson in view of Merril and Tarr fails to explicitly teach, or otherwise suggest, a method of simulating an interventional procedure simulation system including "simulating said at least one instrument with respect to a set value representing a stiffness of said simulated vessel, a rest diameter of said self expanding tool, an initial inner diameter of said simulated vessel and a spring constant for said self expanding tool" as recited in independent claim 6.

As such, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection to independent claim 6.

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**CONCLUSION**

Accordingly, in view of the above, reconsideration of the rejections and allowance of each of claims 1-7 in connection with the present application is earnestly solicited.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicant hereby petitions for a three (3) month extension of time for filing a reply to the outstanding Office Action and submit the required \$550.00 extension fee herewith.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

HARNESS, DICKEY, & PIERCE, P.L.C.

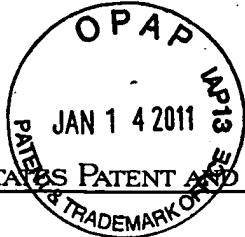
By

John A. Castellano, Reg. No. 35,094

*CDW*  
JAC/CDW:ljs  
P.O. Box 8910  
Reston, Virginia 20195  
(703) 668-8000

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## CONFIRMATION NO. 6867

30593  
 HARNESS, DICKEY & PIERCE, P.L.C.  
 P.O. BOX 8910  
 RESTON, VA 20195

## FILING RECEIPT



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## Applicant(s)

Jan Grund-Pedersen, Kullavik, SWEDEN;

**Power of Attorney:** The patent practitioners associated with Customer Number 30593.

## Domestic Priority data as claimed by applicant

This application is a 371 of PCT/SE03/01892 12/03/2003  
 which claims benefit of 60/430,364 12/03/2002

## Foreign Applications

SWEDEN 0203569-9 12/03/2002

**If Required, Foreign Filing License Granted:** 02/26/2007

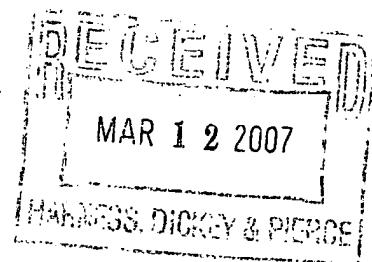
**The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is US10/538,005**

**Projected Publication Date:** 06/07/2007

**Non-Publication Request:** No

**Early Publication Request:** No

**\*\* SMALL ENTITY \*\***



**Title**

Interventional simulator system

**Preliminary Class**

128

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